

K093762



DEC 20 2010

510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Amnon Talmor Regulatory Affairs Specialist Telephone: 610-719-5446 Facsimile: 610-719-5102 Email: talmor.amnon@synthes.com
Date Prepared:	November 29, 2010
Trade Name:	Synthes Zero-P
Common Name:	Intervertebral fusion device
Classification:	21 CFR 888.3080 Intervertebral fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel Product Code: ODP
Predicate Device:	Synthes Zero-P System is substantially equivalent to the Synthes Zero-P System (K072981).
Device Description:	<p>The Synthes Zero-P is a radiolucent and radiopaque cervical intervertebral body fusion device. The Zero-P is composed of a PEEK (ASTM F2026) spacer with a radiopaque marker (ASTM F136-2a), a titanium alloy anterior plate and screws (ASTM F1295). The screws are inserted through the plate into the adjacent vertebral bodies and lock securely to the plate using a tapered-thread locking mechanism.</p> <p>The Synthes Zero-P is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions. This line extension covers the addition of sterile screws.</p>
Intended Use / Indications for Use:	The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.
Comparison of the technological characteristics of the device to the	The Synthes Zero-P device is substantially equivalent to its predicates in indications, fundamental scientific technology, material, mechanical performance, surgical technique, screw fixation and design.

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predicate device:	
Performance Data (Nonclinical and/or Clinical)	Mechanical and clinical data and conclusions were not needed for this device. The enclosed information demonstrates the subject device is as safe, effective and performs as well as the predicate.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Synthes Spine
% Mr. Amnon Talmor
Spine Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, PA 19380

Re: K093762
Trade/Device Name: Synthes Zero-P
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 29, 2010
Received: November 30, 2010

Dear Mr. Talmor:

This letter corrects our substantially equivalent letter of December 20, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K 093762
(if known)

DEC 20 2010

Device Name: Synthes Zero-P

The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.


Prescription Use ☒ X
(21 CFR 801 Subpart D)

AND / OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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